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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,456	06/22/2005	Frans Eduard Janssens	JAB 17341-PCT-USA	1422

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
09/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,456	JANSSENS ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8 and 13-18* is/are allowed.

6)☒ Claim(s) *11,12 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 and 11-19 are pending in the application.

This action is in response to applicants' amendment dated June 13, 2008. Claims 1-8, 11, 12 and 15-18 have been amended, claim 10 has been canceled and claim 19 is newly added.

Response to Arguments

Applicant's arguments filed June 13, 2008 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1 in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that "the two references submitted provide sufficient corroboration to support the breadth of claims 11 and 12, as presently amended". The listing of references in the remarks is not a proper information disclosure statement. Additionally both of the references are not considered prior art as they were published after the filing date of the instant application. As stated in the last office action it is difficult to treat many of the disorders claimed herein. The first reference cited by the applicants', Duffy, R., Expert Opin. Emerg. Drugs indicates that at present (2004) there is no specific treatment for IBS, pancreatitis and cystitis of the bladder, and the major issue to be addressed is: how realistic is the assumption that NK1 receptor blockade will be effective against all of these varied therapeutic targets? That is depression, anxiety, emesis, asthma, cough, migraine headache pain, irritable bowel syndrome, cystitis of the bladder, etc. The second reference cited by the

applicants', Albert et al., Expert Opin. Ther. Patents indicates that at present (2006) there is no antagonists of NK1r in addition to NK3r and that any potential involvement of NK2r antagonism remains even more speculative for CNS-directed therapeutic indications. Albert also indicates that the development of neurokinin antagonists as drugs has been particularly difficult. Despite great promise, intense research and numerous clinical trials, antagonists of NK1r and NK2r have failed to deliver new therapeutic agents for peripherally or centrally directed diseases. The one exception is Merck's NK1r antagonist, aprepitant, which had been investigated and developed (then later withdrawn) as an antidepressant, but was approved for emesis. In addition, interest still remains in NK2r antagonist development for CNS disorders; for example, the NK2r antagonist saredutant is currently in Phase III evaluation for depression according to the intranet site of Sanofi-Aventis. Apart from these, it is clear that research and development of NK3r antagonists for schizophrenia and other CNS disorders is now accelerating and recently disclosed results (although incomplete) are very positive. Thus the state of the art after the time of filing was speculative with respect to the treatment of many of the diseases as claimed herein.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Additionally, the specification does not reasonably provide enablement for "tachykinin mediated conditions". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of

"tachykinin mediated conditions" cannot be deemed enabled. The term "tachykinin mediated conditions" covers a broad array of different disorders that have different modes of action and different origins.

The great majority of these have no treatment at all, and of those that do, none or virtually none have been treated with such inhibitors as are disclosed here. The great diversity of diseases falling within the "tachykinin mediated conditions" category means that it is contrary to medical understanding that any agent (let alone a genus of trillions of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task. Further, what little success there has been does not point in this direction.

Claims 11, 12 and newly added claim 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) in the last office action, which is hereby **withdrawn**.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3a), 3b), 3d), 3e) and 3f)

in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3c) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

c) Claim 11 recite tachykinin mediated conditions and that those skilled in the art would know which disorders constitute a tachykinin mediated condition. Claim 11 is to the method of treating a tachykinin mediated condition. However, tachykinin mediated condition does not provide for the modulation and/or treatment of every disease and/or disorder claimed herein. The rejection of claim 11 is on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the modulation of the tachykinin receptor. The scope of diseases and/or disorders associated with the activity of tachykinin could alter over time. The applicants' are not entitled to preempt the efforts of others. Thus the applicants have not set forth the metes and bounds of the claim.

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

Allowable Subject Matter

4. Claims 1-8 and 13-18 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds, compositions and process of preparing the compounds of formula (I) as claimed herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624